Impact of the interruption of a large heart failure regional disease management program on hospital admission rate: a population-based study

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Heart failure (HF) is a major public health problem, affecting approximately 1% to 2% of the adult population in developed countries, and up to ≥10% in people aged 70 years or more. [1] The syndrome is characterized by repeated hospitalizations and high mortality. [2] It is the main cause of hospitalization for patients over the age of 65 in developed countries, with a death rate reaching 25 % during the first year after hospital discharge [3]. Moreover, the cost of HF accounts for 1% to 2% of total healthcare expenditures, and it is largely driven by hospitalization [4]. Therefore, preventing HF hospitalizations is a major health care objective. Heart failure disease management programs (HF-DMPs) are based on structured follow-up, patient education, optimization of medical treatment, psychosocial support, and improved access to care. Their efficacy has been proven with the highest level of evidence through meta-analysis of randomized controlled trials (Level of evidence A). Accordingly, they are strongly recommended (Grade I) in HF guidelines to reduce the risk of CHF hospitalization. [2,5]. In France, a regional HF-DMP (ICALOR program) was established in 2006 in Lorraine, applying all major components of recommended DMPs as per ESC guidelines. Patients were eligible for enrolment upon discharge from a hospitalization for HF, received intense and recurrent education upon and after discharge and received specially trained HF nurses' home visits, 8 times a year on average. All routine medical data were captured on an electronic medical record accessible to health care professionals identified by the patients. These received and acted upon automatic alerts prompted by meaningful change in a prospectively defined core set of relevant data. A coordination staff monitored compliance of stakeholders with the program. Recruiting centres included all main public and private hospitals and cardiology practices in Lorraine (2,3 million inhabitants). Consistent with pre-existing evidence; the ICALOR program was proven to decrease both HF hospitalizations [6] and all-

cause mortality [7], stabilizing HF hospitalization rates progression in Lorraine while those observed overall in France progressed by approximately 3.5% annually. These results were in line with the results of previous randomized trials, and confirmed the substantial benefit of HF-DMP on both outcomes of interest in a whole, i.e. unselected, population of CHF patients using observational designs. However, although the program was cost-effective [6], changes in health policy led regional French health authorities to stop ICALOR funding, resulting in a cessation of inclusion and follow up in the HF-DMP by the end of 2013.

This observational real life study offers a unique opportunity testing an Off-On-Off design using medico administrative data to assess the effectiveness of complex health interventions. The objective of this study was to assess the impact of ICALOR cessation on the HF hospitalization rates in the Lorraine region as compared to the rest of France, where no such large DMP was implemented. We hypothesized that HF readmissions rates should increase in the Lorraine region after the cessation of ICALOR, catching up with the overall rate in France.

Methods

This comparative Off-On-Off interrupted time series study was based on data from an anonymous national comprehensive database.

Data collection and outcome

Methods were similar to that used in the first study assessing ICALOR effectiveness [6] with six additional later time points, i.e. every year from 2010 to 2016. Briefly, Data from the national diagnostic related group (DRG), a nationwide comprehensive database (Programme de Médicalisation des Systèmes d'Information-PMSI) were used [8]. HF hospitalization was defined by the ICD-10 code I50 as the main diagnosis. All discharge summaries related to HF hospitalizations between January 1st, 1999, and December 31st, 2016 in all residents in France were included.

Statistical analysis

The annual numbers of HF hospitalizations were identified for the Lorraine region and compared to all other regions in France. Both spatial series were normalized such that they start with the same value (100) in 1999. In all the other regions than Lorraine the model assumed that the hospital admission rate increased linearly over time (from 1999 to 2016) with a constant increase. In the Lorraine region, three time periods were considered: from 1999 to 2005 (first Off-period), from 2005 to 2013 (On-period), from 2013 to 2016 (second Off-period). Then, a linear model was fit with a piecewise constant slope to the data. An ANOVA was then performed for each of these three periods to test if the increases in Lorraine region and in all the other regions in France were the same.

Results

Over the observation period, a cumulated total number of 3,429,989 HF hospitalizations were registered in all the other regions than Lorraine France and 133,803 in the Lorraine region, resulting in an average of 190,555 and 7,434 HF hospitalizations per year, respectively. The estimated increase in all the other regions than Lorraine France, i.e. the slope of the estimated model, was 3.97% per year (Figure 1).
Through the three periods, the following results were observed:

- Before ICALOR implementation (from 1999 to 2005, first Off-period) the annual HF hospitalizations increase observed in Lorraine did not differ from the one observed in the rest of France (+2.90% vs. +3.97%, p=0.95);
- During ICALOR active implementation period (from 2006 to 2013, On-period) a slowdown was observed for HF hospitalizations in Lorraine; the estimated increase during this period was statistically slower than the one observed in the rest of France (0.79% vs. +3.97%, $p < 0.001$);
- After ICALOR cessation (from 2014 to 2016, second Off-period), the annual HF hospitalization increase observed in Lorraine did not differ from the one observed in the rest of France (3.24% vs. 3.97%, p=0.70), and was faster than the one observed during the previous On-Period in the Lorraine Region.

Discussion

This national study, using a large comprehensive database including more than 3 million hospitalizations, with a long follow-up duration, shows very clear results confirming the effectiveness of multidimensional HF-DMP on HF hospitalizations. The potential benefit of the program was estimated at minus 1533 hospitalizations in 2013 (16% of CHF hospitalizations in the region) [6]. This benefit stopped right after the program interruption and therefore suggests a deleterious impact of this ill advised interruption on HF patients' health among Lorraine citizens.

This very marked on/off/on temporal evolution is in fact a strong argument in favor of the effectiveness of the intervention. These results confirm the recommendations in favor of multidisciplinary healthcare programs. [2, 5], based on numerous trials and studies in experimental conditions or real life on a smaller scale [9,10,11]. Our study highlights the value of multidimensional HF DMPs at the population level, from the point of view of the organization of the health system. It is therefore necessary to integrate this type of care and to generalize it to all patients, beyond the limited existing programs in certain centers (e.g. in France only 5% of heart failure patients benefited from an education program [12], this activity being left to the initiative of the hospitals without real strong incentives). In this typical case of DMP, grade I level of evidence A health interventions cannot be implemented without a strong buy in and support from policy makers, driving the needed, yet feasible and cost effective changes in health care organisation. Indeed, beyond the experiments and local initiatives, such programs cannot be generalized without political will.

Our study shows the overall effectiveness of the program. However, it does not allow for a mechanistic analysis exmining the efficacy of each of the components of the multidimensional program and their potentially synergistic effects.

From a methodological point of view, our results emphasize the interest, the feasibility and the low cost of quasi-experimental designs using medico-administrative data in effectiveness research. Since their definition by Campbell and Stanley in 1963 [13], these designs have been a major tool for health policy research [14]. Now, the ease of access to large databases allows a greater use of these designs in clinical research, in addition to RCTs, for evaluating efficacy from a population perspective. Results from these studies might be helpful for public health decision-making regarding complex interventions [15].

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Figure 1 : Trends of heart failure hospitalizations in Lorraine and France (without Lorraine) over the period 1999 to 2016. A national observation study using medico-administrative data.